K062361

Conclusion:

OCT 2 3 2006

Applying 2 to 6 drops of samples to the Innovacon hCG Ultra Test Devices yielded correct results as read at 3 or 5 and 10 minutes after sample application. However, Innovacon recommends using 3 drops of the urine or serum sample to obtain the best test result, as prescribed in our package insert.

XV. 510(k) Summary

Device Names:

Innovacon™ hCG Ultra Test Device

Common Name:

Pregnancy Test Kit, Professionals

Medical Specialty:

Clinical Chemistry

Intended Use:

The Innovacon™ hCG Ultra Test Device is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. It is for professional in-vitro diagnostic use only

Device Description:

The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine or serum specimens to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

The Innovacon™ hCG Ultra Test Device is a rapid test that qualitatively detects hCG at the sensitivity of 10 mIU/mL in serum and 20 mIU/mL in urine. The cutoff concentration of this test has been standardized to the World Health Organization Fourth International Standard for Chorionic Gonadotropin (NIBSC Code: 75/589). At the level of claimed sensitivity, the hCG Ultra Test Device

shows no cross-reactivity interference from the structurally related glycoprotein hormones FSH, LH and TSH at extra high physiological levels.

Clinical Studies:

A clinical study was conducted in three sites in the U.S. by healthcare professionals with varying educational backgrounds and laboratory experience and demonstrated performance equivalency between the Fisher Sure-Vue Serum/Urine hCG-STAT test and the Innovacon hCG Ultra Test Device by professionals. The POL study demonstrated high degree of reproducibility and precision of the Innovacon hCG Ultra Test Device

The POL sites also found the Innovacon hCG Ultra Test Device very easy to use, and that they have had no trouble understanding the labeling, reading the instructions, or interpreting the results.

Additional Laboratory Studies:

Additional laboratory study results on performance including specificity, interference substances, urinary pH, urinary specific gravity, dose hook effect, time flexibility, and sample volume flexibility studies are also included in this submission. These results indicate that the Innovacon hCG Ultra Test Device is robust and will give accurate results under many adverse conditions.

Substantial Equivalency on Performance:

The overall performance data indicate that the Innovacon hCG Ultra Test Device is safe, effective and substantially equivalent to the Fisher Sure-Vue Serum/Urine HCG-STAT legally sold in the U. S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Vice President, Regulatory Affairs
Innovacon Inc
4106 Sorrento Valley Blvd.
San Diego, CA 92121

OCT 23 2006

Re: k062361
Trade/Device Name: Innovacon™ hCG Ultra Test Device
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: August 11, 2006
Received: August 14, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

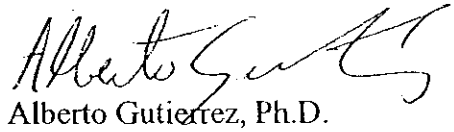
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

V. Indications For Use

510(k) Number (if known): K062361

Device Name: Innovacon™ hCG Ultra Test Device

"Indications for Use":

Innovacon™ hCG Ultra Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. It is for healthcare professionals only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K062361